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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,955	05/22/2006	Anthony Wills	133088.00801(P37233US)	1670
35151	7590	03/06/2008		
Pepper Hamilton LLP 400 Berwyn Park 899 Cassatt Road Berwyn, PA 19312-1183			EXAMINER SMITH, RICHARD A	
			ART UNIT 2859	PAPER NUMBER
			MAIL DATE 03/06/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/560,955	<b>Applicant(s)</b> WILLS, ANTHONY	
	<b>Examiner</b> R. Alexander Smith	<b>Art Unit</b> 2859	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 December 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 13-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 13, 15-17 and 19-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,526,752 to Perlman et al. in view of US 5,228,573 to Pavelle et al.

Perlman et al. discloses a medical device (Figure 1) and method of informing of the status of said medical device sealed in gas-tight packaging (12), wherein the medical device comprises a latent dye marking (13) irremovably adhered to the surface of the device comprising oxidisable dye (col. 1 line 37) which becomes visible after a predetermined time following exposure of the device to air (col. 1 line 65-67) and further comprising a reducing agent (col. 1 line 42), wherein prior to the opening of the packaging the marking remains invisible and undeveloped and wherein after a period of time from the opening of the packaging the marking becomes visible to yield a warning message in the visible spectrum (col. 1 lines 59-64).

Perlman et al. does not disclose that the latent marking does not become visible immediately following exposure of the medical device to air, the predetermined time is minutes, and the predetermined time is from 3 minutes to 2 weeks.

Pavelle et al. discloses a method of packaging involving sealing an air sensitive reagent which changes color upon contact with air which can be used as a tamper or package integrity indicator; and, also discloses that a semi-permeable membrane can be added to allow the same reagent to function as a shelf-life indicator (abstract, column 1 lines 6-29 and 55-68) in order to address time-sensitive materials and products which have a shelf life or which deteriorates (column 1 lines 19-27) and can be timed to react on a scale identical to the shelf-life of the product or its useful life (column 4 lines 40-45). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the medical device and the method of informing, taught by Perlman et al., to include a semi-permeable membrane and to change the latent display to indicate a maximum effective shelf-life or useful life, i.e., not immediately visible, as suggested by Pavelle et al., in order to allow the device and method to also function as a shelf-life or useful life indicator.

With respect to predetermined time being minutes, and 3 minutes to 2 weeks: As stated above, Pavelle et al. teaches that the color change can be timed to react on a scale identical to the shelf-life of the product or the useful life: Therefore with respect to the time being minutes and 3 minutes to 2 weeks, these limitations are only considered to be the "optimum" values of the predetermined time of the device and method disclosed by Perlman et al. as modified by Pavelle et al. as stated above, that a person having ordinary skill in the art would have been able to determine using routine experimentation based, among other things, on the matching the color change to the shelf life or useful life of the medical device. See In re Boesch, 205 USPQ 215 (CCPA 1980).

3. Claims 14 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perlman et al. and Pavelle et al. as applied to claims 13, 15-17 and 19-24 above, further in view of US 4,502,605 to Wloszczyna and US 5,997,964 to Klima, Jr.

Perlman et al. and Pavelle et al. together teach all that is claimed as discussed in the above rejections of claims 13, 15-17 and 19-24 except for the marking is etched into the surface and obscured by an opaque layer prior to exposure of the device to air, wherein the opaque layer changes to clear following said exposure.

Wloszczyna discloses a container wherein a layer (6) is added which changes from red to colorless quickly (column 5 lines 55-60) in order to indicate that the container has been opened or tampered (column 1 lines 11-17). Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention was made to add the opaque layer means disclosed by Wloszczyna to the device for indicating shelf life or useful life, disclosed by Perlman et al. as modified by Pavelle et al., in order to provide an addition means which indicates tampering or opening.

Klima, Jr. discloses a layered indicator and teaches that ink can be stabilized in or on a surface by etching (column 5 lines 53-57). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device and method, taught by Perlman et al. and Pavelle et al. by having an etched latent mark, as suggested by Klima, Jr. in order to stabilize the ink/dye in or on the surface should the surface be non-absorbing.

Application/Control Number: 10/560,955  
Art Unit: 2859

Page 5

*Response to Arguments*

4. Applicant's arguments filed December 31, 2007 have been considered but are moot in view of the new ground(s) of rejection.

*Conclusion*

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The prior art cited in PTO-892 and not mentioned above disclose related devices and methods.

Art Unit: 2859

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to R. Alexander Smith whose telephone number is 571-272-2251. The examiner can normally be reached on Monday through Friday from 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dean A. Reichard can be reached on 571-272-1984. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R.A.Smith/

R. Alexander Smith  
Primary Examiner  
Art Unit 2859

March 12, 2008